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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/782,171	PATI ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The finality of the action, mailed 4/2/04, has been hereby withdrawn due to newly set forth rejections as summarized below.

Applicant's amendments and remarks, filed 9/18/04, are acknowledged and have been entered.

Applicant's arguments, filed 9/18/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim 16 is herein under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "nucleic acid sequence" in lines 17-18 and 20. There is insufficient antecedent basis for this limitation in the claim as it is unclear if these limitations are referring to the first or second nucleic acid sequence described in the claim. Clarification of this issue via clearer claim wording is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Layne et al. (P/N 5,841,975) in view of Seilhamer et al. (WO 96/23078) and Glitho et al. (P/N 5,999,973).

Layne et al. describe a method and apparatus for sharing integrated services with remote clients involving biological material (abstract, item 200 in Figure 7, and col. 11, lines 55-57). Layne et al. describe a customer generating commands (request) via a computer communication program link and the internet (websites) and sending specimens to an automated lab (abstract; Figure 4; col. 8, lines 30-35; and col. 15, lines 22-25). Layne et al. describe the customer is enabled to define the processes to be performed by entering information into the program via

control tools (col. 8, lines 30-32). Layne et al. describe obtaining and transmitting results, which is reasonably interpreted as more than one product or service, to the remote client (abstract). Layne et al. also describe creating and entering output and analyses for the results (report) into a database as seen in Figure 4. Layne et al. depict this process as circular and continuous (Figure 4) which suggests that multiple, including second requests (note the claims do not require the first and second nucleic acid sequences to necessarily be different), can be made by the customer as stated in claim 16. Layne et al. describe how the remote customer can have the data stored into a database and request analyses to be performed on data generated by their and other users' data on the database (col. 8, lines 45-51 and col. 11, lines 5-9). Layne et al. describe using instruments in an automated test instrument suite which offers selections of standardized tests, so if assays of biological specimens are desired, then selections of standardized assays are offered within process control tools including a database (Figure 6 and col. 10, lines 41-46) which represents a pull-down menu. Layne et al. describe researchers entering information about specimens, treating agents (drugs), cell cultures, data (results), and other items (col. 10, lines 52-63) which represents a report. Layne et al. describe ascertaining amount of materials for a test and checking either that it can proceed or report that it cannot do so and state a cause (col. 9, lines 21-26). Layne et al. describe evaluating whether specimens and assays meet quality control standards (col. 11, lines 9-12) which represents a verification that the customer is in good standing. Layne et al. describe privileges designating who has permission to view or use the data which may include the researcher only, certain collaborators, or unrestricted access by all (col. 11, lines 23-29) which represents a private or semi-private secured transmission line. Layne et

al. do not describe the nucleic acid clone product ordered from the customer that is the noted specie election in the instant application.

Seilhamer et al. describe obtaining cDNA from a customer as well as storing relevant supplier ID information in a table that is stored in a database (page 9, lines 25-30). Seilhamer et al. describe performing a cloning process on the cDNA (Figure 2 and page 9, lines 31-32). Seilhamer et al. describe using multiple clones that may or may not be different (page 15, lines 6-10). In Figure 2, Seilhamer et al. depict the cloning process followed by sequencing which is stored in a database (page 14, third paragraph) and sequence comparison (page 15, first paragraph) which is reasonably interpreted to mean that searchable genomic data were created as stated in claim 16. Seilhamer et al. describe the sequences may be compared to known sequences in genetic databases (page 15, first paragraph to page 17, first paragraph). Seilhamer et al. describe during the sequence comparison process, the multiple clones may contain all or parts of the same gene/allele (page 15, first paragraph) which is reasonably interpreted as checking for wholly or partially redundant information within the databases (genomics reports) as stated in claim 16. Seihamer et al. describe that information associated with the steps in Figure 2 (including sequence comparison) is stored in a database (page 6, lines 6-9) which is reasonably interpreted to include the updating step. Seilhamer et al. describe using an interface with an integrated ethernet network (Figure 1). Seilhamer et al. describe various fields, such as COLLABORATOR_ID (110) (customer identification number), BIO_SOURCE_ID (130) (field for nucleic acid sequence), and CULTURE_ID (140) (field for genomic product), cDNA CONSTRUCTION_ID (170) (field for another genomic product) (Figure 3A and B) and CLONE_ID (Figure 4) as now stated in instant claim 16. Seilhamer et al. describe suppliers and

vendors (Figures 3A and 6). Seilhamer et al. describe databases that include nucleic acids, proteins, and motifs (page 3, lines 36-37).

Glitho et al. describe data access from a customer administrative system and database network elements by eternal data access through web-server and an Internet connection (col. 2, lines 51-56). Glitho et al. describe external entity data transactions, queries, and modifications passing through the interface with logic (including redundancy logic) to specify based on external entity request, the action or actions that need to be taken to implement the request as well as proper routing to the request to the customer system for handling (col. 2, line 59 to col. 3, line 4). Glitho et al. describe maintaining transaction, redundancy, query oriented, and data migration logic functionalities based on the received request the actions to be taken and to route the request accordingly (col. 3, lines 8-12). Glitho et al. describe redundancy logic is utilized in conjunction with transaction logic to identify for each received subscriber data order the customer system and database network elements that are affected by the order (both primary and redundant database network elements (second requests)), to identify particular actions to be taken by customer system and database network element in connection with order (queried response), to identify commands needed to effectuate those actions (i.e. to proceed with actions), to convert the commands, and issue the commands (i.e. to proceed) (col. 3, line 56 to col. 4, line 7) which represents querying a customer to proceed if there is redundancy in the requests. Glitho et al. describe the interface utilizing query oriented logic to query the customer system regarding the stored permanent information and performing search requests resulting in proper queries for the customer system for handling (col. 4, lines 21-35). The customer system handles the query with search results sent back to interface resulting in signals originated by the search request

(col. 4, lines 35-40). Glitho et al. describe routing properly formatted commands to necessary nodes for handling (col. 4, lines 50-54). The above Glitho et al. descriptions represent querying a customer to proceed with a second request if said second request is redundant, as stated in instant claim 16.

Layne et al. state their apparatus and method satisfies a need to provide a wide variety of adaptable services to globally-distributed remote clients (col. 15, line 66 to col. 16, line 10). Layne et al. state there is a need to integrate capabilities of available automated equipment to permit processes to be performed instead of solely relying on special-purposes devices (col. 16, lines 1-4). Seilhamer et al. state that most analysis on genetic information was performed using chemical methods in a laboratory (page 1, lines 27-28). Seilhamer et al. state computerized research tools at the time only performed limited comparisons to sequence information and state a need to store and manipulate diverse information involving cDNA sequences and the cells from which they were derived in order for scientists to analyze data efficiently in diagnostic and drug development research (page 1, line 33 to page 2, line 5). A person of ordinary skill in the art would have been motivated to enhance the integrated internet (website) services stated by Layne et al. by including additional features in the method to further increase the efficiency and availability of research materials, as stated by Seilhamer et al., as well as maintaining security, as stated by Glitho et al. (col. 2, lines 41-48) to globally-distributed remote clients. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the nucleic acid clone supplies and associated sequence comparison information and field identifiers (as stated by Seilhamer et al.) in a manner to be available to remote clients (as stated by Layne et al.) with secure connections (as stated by Glitho et al.) as this would

provide a more efficient, safe, and global use of tools for diagnostic and drug development research as stated by Seilhamer et al., Layne et al., and Glitho et al.

Thus, Layne et al., in view of Seilhamer et al. and Glitho et al., motivate claim 16.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

October 19, 2004

ARDIN H. MARSCHEL
PRIMARY EXAMINER